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Institutional Administrator's Manual for Laboratory Animal Care and Use

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Institutional Administrator's Manual for Laboratory Animal Care and Use

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EXECUTIVE SUMMARY

This booklet entitled "Institutional Administrator's Manual for Laboratory Animal Care and Use" (referred to as the "Manual") is a concise guide for institutional administrators who supervise laboratory animal care and use programs at their institutions.

A quality program is critical for quality science. There are ethical, legal, and public relations reasons for ensuring that such programs meet contemporary standards and guidelines for animal use. The Public Health Service Policy on Humane Care and Use of Laboratory Animals (referred to as the PHS Policy), the U.S. Department of Agriculture's (USDA) Animal Welfare Regulations and the National Academy of Science's National Research Council's, the Guide for the Care and Use of Laboratory Animals (Guide), contain the standards and requirements which impact most significantly on institutional animal care and use programs. These requirements center around the establishment of Institutional Animal Care and Use Committees (IACUCs) with defined responsibilities and authorities for protocol review, training programs, specifications for caging systems, requirements pertaining to veterinary care and surgical procedures, and the establishment of occupational health programs.

No program can be successful unless personnel using or caring for laboratory animals are well qualified by training or experience. Lines of authority, policies, and procedures for animal care and use programs are to be set forth in writing, well understood, and implemented by all persons involved.

Pitfalls to avoid are: absence of clear lines of authority and responsibility; administrative complacency; failure to inform and assure employees not involved in animal care or use that there are appropriate programs to safeguard animal welfare; failure to establish procedures to ensure administrative awareness of the status of the programs; resolution of disputes without necessary pertinent data; and, in academic institutions, ignoring resistance on the part of some individuals to participate in programs involving the use of animals.

Costs for animal care and use programs have escalated considerably over the last several decades. Nevertheless, adequate funds for operation of sound animal care and use programs must be budgeted by research institutions.

There are numerous regulations and information sources which should be familiar to personnel who manage animal care and use programs. These are cited and described throughout the Manual and in Appendix B.

INTRODUCTION

Institutional administrators who are responsible for animal care and use programs should find this Manual of value. In brief, it attempts to answer the following general questions:

-- "What constitutes a quality animal care and use program?"

-- "What is necessary to meet ethical, legal, and granting agency requirements for laboratory animal care and use?"

-- "How shall an institution evaluate the quality of its animal care and use program?"

In addition to answering these general questions, the Manual addresses a number of frequently asked questions contained in Appendix A.

For purposes of this publication, the term "laboratory animals" refers to vertebrate animals only.

PART 1

INSTITUTIONAL INTERESTS

PART 1 - INSTITUTIONAL INTERESTS

1.1 QUALITY SCIENCE
1.2 LEGAL REQUIREMENTS
1.3 REQUIREMENTS OF FUNDING AGENCIES
1.4 LIABILITIES AND RISKS

PART 1

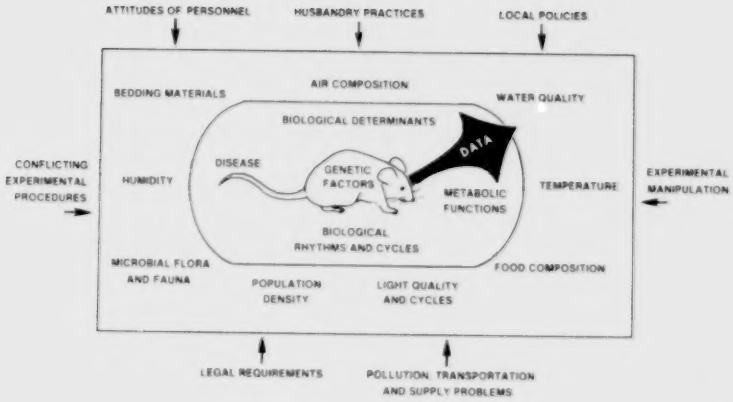
INSTITUTIONAL INTERESTS

1.1 QUALITY SCIENCE

Quality science demands quality animal care! Since the goal of biomedical research is good science, it is within the self-interest of all research institutions to have a good animal care and use program. In research involving animals, the most significant variables are the animals themselves. There are multiple factors unrelated to the experimental design which can influence an animal's physiological and behavioral status (see Figure 1 entitled, "Non-experimental Factors Influencing Animal Physiology and Behavior," page 6); therefore, it is imperative that these factors be critically controlled to minimize data variability. These controls can best be accomplished with a well managed, high quality animal care and use program.

FIGURE 1

NON-EXPERIMENTAL FACTORS INFLUENCING ANIMAL PHYSIOLOGY AND BEHAVIOR



After illustration provided by Dr. William J. White, The Milton S. Hershey Medical Center

1.2 LEGAL REQUIREMENTS

Contemporary laws and guidelines require that animal experimentation precede human application of new medical procedures, drugs, and devices (See, for example, Declaration of Helsinki, Appendix B, Section B.1, page 41) and that sound animal care and use programs be implemented by institutions using laboratory animals. The U.S. Government Principles (Appendix B, Section B.2, page 41) provide an ethical framework within which Federal agencies and institutions that receive Federal support are to operate when dealing with issues pertaining to the use of laboratory animals. The Federal Animal Welfare Act, along with its implementing regulations, mandates minimal standards of laboratory animal care. These standards apply to nearly all academic and research institutions and are enforced by the United States Department of Agriculture (USDA) through on-site inspections, most of which are unannounced (for details see Appendix A, Section A.5, page 34, entitled "What is the United States Department of Agriculture (USDA) and its role in enforcing the Federal Animal Welfare Act," and Appendix B, Section B.3, page 42, entitled "Federal Animal Welfare Act").

For those institutions which receive funding from the Public Health Service (PHS), including the National Institutes of Health (NIH), additional requirements must be met. Guidelines mandated by The Health Research Extension Act of 1985 (P.L. 99-158) are incorporated in the PHS Policy on the Humane Care and Use of Laboratory Animals (PHS Policy, Appendix B, Section B.4, page 42). An example of the additional requirements set forth by the PHS Policy, as contrasted to the Federal Animal Welfare Act, is that institutions must place on file in the NIH's Office for Protection from Research Risks (OPRR) an approved Animal Welfare Assurance document detailing their commitment to good animal care and use before they can receive PHS funds. The PHS Policy also requires institutions to follow the recommendations of the Guide (for details, see Appendix B, Section B.5, page 44) in order to be eligible to receive PHS funds to conduct activities involving animals.

There are other Federal laws which may pertain to specific research and academic programs, depending upon the type of work being

done and the species being used. Selected examples of these laws are outlined in Appendix B, Sections B.6 and B.7, pages 45-46.

In addition to Federal laws, regulations, and guidelines there are an increasing number of state and local statutes which affect an institution's research and academic programs involving the use of laboratory animals. Institutional administrators should ensure that procedures are in place to enable them to remain cognizant of and compliant with state and local laws and regulations that may affect their institution's programs.

1.3 REQUIREMENTS OF FUNDING AGENCIES

Governmental agencies other than the PHS (e.g., the National Science Foundation), and many non-governmental funding agencies (e.g., the American Heart Association), may impose additional requirements on animal care and use. Since each agency's requirements may be different, institutional procedures should be in place to assure that these requirements are known and that they are met.

1.4 LIABILITIES AND RISKS

The public is concerned with issues involving the use of animals in research, testing, and education. In particular, there is growing apprehension by the public as a whole, and legislative representatives at all levels, about the use of animals in what some perceive to be inhumane or unnecessary activities. Any institution which uses laboratory animals must not only operate a sound program, but be prepared to be publicly accountable for the program in which animals are involved.

Administrators are well advised to take all necessary steps to assure that visitors, employees, and students are fully aware of the institution's dedication to quality of the animal care and use program. In-house procedures for surfacing and addressing concerns should be established and publicized. This will help reduce misconceptions and

misinformation that could lead to adverse publicity, employee dissatisfaction, or even litigation.

Finally, it is possible that an institution using laboratory animals may encounter public relations difficulties even though it has a quality animal care and use program and even though its employees and students are fully informed. For this reason, it is imperative that procedures be developed which enable institutional administrators to be continually informed of the facts pertaining to their organization's animal care and use programs so that they can be confident that their programs are of high quality, and can accurately respond on short notice to inquiries.

PART 2

COMPONENTS OF A QUALITY ANIMAL CARE
AND USE PROGRAM

PART 2 - COMPONENTS OF A QUALITY ANIMAL CARE AND USE PROGRAM

2.1 THE RESEARCH TEAM
- 2.1.1 Institutional Officials
- 2.1.2 Animal Users
- 2.1.3 Animal Care Staff

2.2 POLICIES, PROCEDURES, RESOURCES, AND FACILITIES

PART 2

COMPONENTS OF A QUALITY ANIMAL CARE AND USE PROGRAM

2.1 THE RESEARCH TEAM

A quality animal care and use program requires the integrated support of many persons, including the institutional officials, the investigators and their research technicians, veterinarians, and the animal care staff. Regulations and guidelines governing the use of laboratory animals apply to all persons involved in animal use, including institutional officials, animal users (investigators and students), and animal care providers.

2.1.1 Institutional Officials

Sustained and visible support from institutional officials is absolutely essential to establishing and maintaining a high quality animal care and use program. They are in positions to influence institutional priorities. They can assure that sufficient monetary and personnel resources are allocated to the institution's program. A high priority for animal care and use requirements on the part of institutional officials can result in direct benefits in terms of resource availability, as well as in many critically important indirect benefits, for example, a rapid response to facility problems by facility engineers.

2.1.2 Animal Users

An animal care and use program cannot succeed without the active support of the scientists and their research technicians. The animal users, with their vested interests are in the best position to define the needs of the institution's research, testing, and educational efforts and to implement experimental designs and animal use procedures which will support both quality science and humane care and use of animals.

2.1.3 Animal Care Staff

The animal care staff, from the director to the animal care technicians, are the persons who work most directly with the experimental animals. They must be dedicated to providing quality animal care and use support and should be well qualified, by training or experience, to handle, and minister to the animals in their care. They should be knowledgeable about the requirements for the species involved, as well as about any special requirements imposed by specific research, testing, or teaching programs.

2.2 POLICIES, PROCEDURES, RESOURCES, AND FACILITIES

Supporting a quality animal care and use program are the personnel, policies, procedures, resources, and facilities which define the program. If an institution has a dedicated, knowledgeable, and interactive staff, it is likely that it will also develop the policies, procedures, resources, and facilities required to support a quality program. With a dedicated staff, less than optimal facilities may be overcome by implementing policies and procedures that encourage sound animal care and use. Although policies and procedures will be different for each institution; they should be documented in writing and promulgated to all persons who have responsibility for animal care and use.

PART 3

KEY ASPECTS OF A QUALITY ANIMAL CARE
AND USE PROGRAM

PART 3 - KEY ASPECTS OF A QUALITY ANIMAL CARE AND USE PROGRAM

3.1 LINES OF RESPONSIBILITY AND AUTHORITY

3.2 THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

- 3.2.1 Establishment
- 3.2.2 Composition
- 3.2.3 Responsibilities

3.3 POLICIES AND PROCEDURES FOR VETERINARY CARE AND ANIMAL HUSBANDRY

- 3.3.1 Facilities and Resources
- 3.3.2 Training Programs
- 3.3.3 Occupational Health Program
- 3.3.4 Communicating With the Public

PART 3

KEY ASPECTS OF A QUALITY ANIMAL CARE AND USE PROGRAM

3.1 LINES OF RESPONSIBILITY AND AUTHORITY

The 1985 Amendments to the Animal Welfare Act include the provision that the "Secretary [of Agriculture] shall require that each research facility establish at least one [Institutional Animal Care and Use] Committee" which "shall be appointed by the chief executive officer" of the institution. In addition, the PHS Policy states that "the Chief Executive Officer [of the research institution] shall appoint an Institutional Animal Care and Use Committee (IACUC)." From these excerpts, it is clear that there is strong regulatory emphasis on senior management level responsibility for animal care and use programs and on institutions managing their programs by use of in-house oversight committees. The philosophy spelled out in these two documents is clearly one of self-regulation, with the committees working closely with the animal users, animal care staff, and the responsible veterinarian(s) (referred to in the Animal Welfare Act as the "Attending Veterinarian") to ensure that high quality animal care and use programs are in place. A unique provision of the PHS Policy is that institutional officials are prohibited from approving protocols or procedures which the IACUC has disapproved.

Regardless of the type of institutional or managerial structure involved, the specific responsibilities and authority of the various persons involved in the animal care and use program should be unambiguously delineated in writing. In addition, the lines of authority should be clearly illustrated and procedures for reporting problems should be included in the written material. Most importantly, all persons involved in the use of or caring for animals should be aware of the procedures for the reporting

concerns about animal care or use (for additional information on the importance of this latter point see "Communicating with the Public," Part 3, Section 3.3.4., page 24).

3.2 THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

3.2.1 Establishment

As noted above, all research institutions which are required to be registered under the provisions of the Animal Welfare Act, or which receive PHS funds, are required by law to establish an IACUC. The Congress and PHS have mandated that institutions establish IACUCs to oversee programs of animal use with the objective that these committees form the foundation for effective self-regulation. Institutions subject to provisions of both the Animal Welfare Act and the PHS Policy, may establish a single IACUC, provided that the committee meets all requirements of both documents. Small institutions which have limited personnel resources may wish to consider consortium type arrangements with nearby organizations in order to assemble sufficient numbers of qualified and interested individuals to an appropriate IACUC.

3.2.2 Composition

The composition of the IACUC is mandated by both the Animal Welfare Act and the PHS Policy (for specific composition requirements, see Table 1 on page 75). While there are some minor differences between the two documents, the intent is that the committees be composed of people qualified to evaluate the programs and proposals under review and who represent several categories of interested people, including scientists, lay persons, and those concerned with humane care and use. In all cases, someone affiliated with the institution in no way other than service on the IACUC, must be included in the committee's membership. Institutions should ensure that persons with expertise in the disciplines involved in local research and teaching programs are selected for service on their IACUCs.

3.2.3 Responsibilities

The PHS Policy requires the IACUC to evaluate the Animal Welfare Program, to identify the deficiencies, and to make recommendations for correction of deficiencies within a reasonable time. The IACUCs are charged by the Animal Welfare Act to inspect, at least semiannually, "all animal study areas and animal facilities" and review, at a minimum, the condition of the animals and practices involving pain. Reports of the inspections and reviews are to be filed with the institution and are to include a description of all "violations" and "deficiencies," as well as minority views. These reports are to be kept on file for at least three years and are subject to review by PHS officials or by the USDA inspectors who may, in turn, forward copies to the USDA for follow-up on deficiencies and violations.

The PHS Policy requires that the IACUC conduct semiannual evaluations of the institution's programs and inspection of its facilities. Reports of these semiannual assessments are to be filed with an "Institutional Official," specified in the Assurance, and need not be forwarded to OPRR unless serious and continuing deficiencies are noted. They are subject to review by OPRR upon request. Annual reporting requirements to OPRR include changes in program or facilities, changes in IACUC membership, and the dates of semiannual evaluations.

The Policy also mandates that the Committee "review and approve, require modifications in (to secure approval), or withhold approval" of those components of PHS funded activities related to the care and use of animals, including any significant changes thereto. In addition, the PHS Policy requires that the IACUC be "authorized to suspend an activity involving animals" until reviewed by higher authority and, as noted previously, the Policy prohibits institutional officials from approving proposed activities disapproved by the Committee.

In accordance with the PHS Policy, animal users must be qualified to accomplish the procedures, and handle the animals involved in their research protocols. It is the IACUC's responsibility to determine if individuals using certain species of animals and conducting procedures on animals are qualified. There are currently no established programs for

"certifying" the competence of investigators or research technicians to conduct animal procedures; thus, institutions must establish in-house criteria by which qualifications are judged. Information regarding the specific responsibilities of the IACUCs are described in Table 1, page 75.

3.3 POLICIES AND PROCEDURES FOR VETERINARY CARE AND ANIMAL HUSBANDRY

The Animal Welfare Act requires that a veterinarian be a member of the IACUC. The PHS Policy is more specific in that it requires that the veterinarian have "training or experience in laboratory animal science and medicine" [with] "direct or delegated program responsibility for activities involving animals at the institution." These requirements imply that the veterinary care program is a key element in a satisfactory animal care and use program. Furthermore, it is intended that the attending veterinarian be a person with some qualifications in laboratory animal medicine. Institutions which currently employ a local veterinary practitioner who might not meet such qualifications may wish to assist the veterinarian in obtaining appropriate training through various continuing education programs.

The NIH Guide states that "proper management of animal facilities is essential to the welfare of animals, validity of research data, and health and safety of the animal care staff," and, it might be added, the health and safety of the scientists using the animals. Furthermore, it is noted that "a good husbandry program provides a system of housing and care that permits the animals to grow, mature, reproduce, and maintain good health" and results in minimizing physiological variations which may affect research data. In practice, a good husbandry program will include not only good facilities and management practices but will also reflect a "caring" philosophy in approaches taken to animal housing, handling, and use. The animal care staff should be directed by a qualified professional, such as a veterinarian or biomedical scientist with advanced training or experience in Laboratory Animal Medicine or Science, or, in the case of small programs, a qualified technologist, with professional support provided in the form of consultants or advisors. The animal care program director must be thoroughly familiar with the various Federal and local

laws and guidelines pertaining to animal care and use programs, as well as laboratory animal science and technology required by a contemporary program.

When attempting to evaluate the credentials of prospective animal care staff personnel, there are two peer-managed certification programs which may indicate the person's relative knowledge and ability levels. In the case of veterinarians, the American College of Laboratory Animal Medicine (ACLAM) is a specialty board recognized by the American Veterinary Medical Association. Diplomate status in ACLAM is attained by examination. In the case of animal care technologists and technicians, the American Association for Laboratory Animal Science (AALAS) administers a certification program with three levels of competency i.e., entry level ("Assistant Laboratory Animal Technician"), mid-level ("Laboratory Animal Technician"), and senior level ("Laboratory Animal Technologist"). Certification at all three levels is by examination. In addition, a number of two- and four-year "veterinary technology" college level programs exist whose graduates have had at least an introduction to laboratory animal science. Additional information pertaining to the certification programs may be obtained directly from ACLAM or AALAS, and on college level programs from the American Veterinary Medical Association (their addresses may be found in Appendix C, Sections C.5., C.6., and C.7., pages 53-54).

The Animal Welfare Act contains two provisions which may significantly impact on laboratory animal husbandry programs in the future, i.e., the Secretary of Agriculture shall establish minimum requirements for "exercise of dogs" and "a physical environment adequate to promote the psychological well-being of [nonhuman] primates." At the time that this Manual was written, regulations implementing these two provisions had not been published; however, institutional administrators should assure themselves that their institution has considered these two aspects of husbandry.

All policies and procedures which implement the institution's animal husbandry and veterinary care programs should be documented in writing and should be made available to all animal users and other persons interested in animal care and use.

3.3.1 Facilities and Resources

Institutional administrators must provide adequate resources for the animal care and use program. While the costs of using animals may be partially recovered from extramural sources, through "indirect costs," reimbursement, and per diem charges, such funding may not cover all costs. Therefore, some level of "core" support from institutional funds will be necessary, especially for capital improvements.

The most successful resource management programs are those in which the IACUC, Animal Care Director, and attending veterinarian work together closely as a team and receive strong support from institutional officials and animal users. Within general guidelines specified by written institutional policies, allocation of animal care and use resources should be managed by the IACUC and/or the Animal Care Director. In many institutions, the IACUC reviews resource allocation policies and procedures, such as animal space allocation and per diem fees, and recommends changes to the institutional administrator. The Animal Care Director is usually the person who manages the resources on a day-to-day basis, having input to policy and procedure decisions through the IACUC and, preferably, by direct advice to the institutional administrators.

3.3.2 Training Programs

The 1985 Animal Welfare Act includes a requirement that research facilities "provide for the training of scientists, animal technicians, and other personnel involved with animal care and treatment" and that the training "include instruction on:

(1) the humane practice of animal maintenance and experimentation,"

(2) research or testing methods that minimize or eliminate the use of animals or limit animal pain and distress,"

(3) utilization of the information service at the National Agricultural Library established [under the Act]," and

(4) methods whereby deficiencies in animal care and treatment should be reported."

The PHS Policy also requires training of personnel and by stipulating that institutions receiving PHS funds abide by the Guide, also requires training programs, with regular participation by research and technical staff. In addition, the Guide states that:

> "It is an institutional obligation to ensure that professional and technical personnel who perform animal anesthesia, surgery, or other experimental manipulations are qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner. Special training programs should be provided for technicians and faculty, as well as undergraduate, graduate, and postgraduate students."

Other than the subject matter mandated by the Animal Welfare Act (see Section 3.3.2., points 1 through 4, pages 22-23), the content of all training programs should be tailored to the internal needs of the institution to ensure relevancy for the participants (e.g., a summary of institutional animal welfare procedures). Since it is usually representative of the institutional animal care and use communities, the IACUC is frequently the best body able to specify the content and format which will accommodate an institution's needs.

Several successful training programs have included relatively short sessions, usually devoted to mandatory topics and other generally applicable didactic material (e.g., internal policies and procedures), followed by longer, and usually voluntary, hands-on sessions covering specific topics such as handling of various species or accomplishment of specific experimental procedures. In many cases, researchers have participated as teachers, providing hands-on training in specific techniques with which they have particular expertise. Some smaller institutions, with limited in-house resources, have found it valuable to establish cooperative arrangements with neighboring institutions for training programs.

Records of participation by personnel in training programs should be maintained, and will probably be required by the implementation regulations for the Animal Welfare Act Amendments. Furthermore,

documentation of participation in the training programs may be valuable to the IACUC for determining qualifications of individuals wishing to work with laboratory animals.

3.3.3 Occupational Health Program

The Guide states that "an Occupational Health Program is mandatory for personnel who work in laboratory animal facilities or have substantial animal contact." Depending on the animal species maintained and the type of activities conducted, an acceptable Occupational Health Program should include some or all of the following: preemployment, periodic physicals, and termination of employment physical examinations; provisions for protective clothing and equipment; a standardized mechanism for reporting accidents and gaining treatment; serological monitoring for exposures to specific diseases and provision of specific vaccinations; zoonoses surveillance, both as related to the animals and their handlers; and monitoring for exposure to potentially hazardous biological, chemical, or physical agents (for more details, see Appendix D, page 57).

3.3.4 Communicating With The Public

It is essential that institutions using experimental animals communicate effectively with members of the public with interests in the use of animals in research. Institutional administrators responsible for animal care and use programs should be well informed about their programs, as well as animal use issues in general, so that they may be effective spokespersons for their organizations. Professional and technical staff, as well as students, are important participants in an institution's interactions with the public.

All segments of the institutional community should be aware of the significance of the work in which animals are used, the quality of the institution's animal care and use program, and the extent of the institution's commitment to high scientific standards through high quality animal care and use. It is also important that all members of the institutional community know how to report their concerns about animals internally, without fear of reprisals, and that reasonable concerns be promptly addressed so that there is no need to go outside the institution.

Some institutions have been proactive in this regard, seeking opportunities to publicize their programs which use laboratory animals in ways which illustrate that important work is being accomplished in ethical and humane ways. Others have been required to respond to public inquiries resulting from allegations of inhumane animal use or a substandard animal care and use program. In such instances the most effective responses have ensued when the institutional spokesperson, frequently an institutional administrator, was able to address specific allegations quickly, with accurate and factual information. When public interest in animal care and use is expressed, it has been shown to be helpful for institutions to have on hand prepared statements about the institution's policies and commitment to humane and appropriate animal care and use, the quality of its animal care and use program (any accreditation and the extent of protocol review should be mentioned, as appropriate), and brief summaries of the value and importance of any specific animal use under scrutiny (such summaries may be a required component of protocol review procedures). All written material intended for public distribution should be written in language understandable to nonscientists with high school reading abilities.

APPENDICES

and

TABLES

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APPENDIX B: LAWS AND GUIDELINES

APPENDIX C: SELECTED RESOURCE SOURCES

APPENDIX D: OCCUPATIONAL HEALTH PROGRAM

APPENDIX E: SELF-EVALUATION OUTLINE

APPENDIX F: ACRONYMS OF ORGANIZATIONS AND REGULATORY REFERENCES INCLUDED IN THIS MANUAL

TABLE 1: INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

APPENDIX A

FREQUENTLY ASKED QUESTIONS ABOUT
ANIMAL CARE AND USE PROGRAMS

APPENDIX A - FREQUENTLY ASKED QUESTIONS ABOUT ANIMAL CARE AND USE PROGRAMS

A.1 How shall institutional administrators gather data to evaluate the quality of the animal care and use programs?

A.2 What are the pitfalls?

A.3 How can professional staff be encouraged to support the animal care and use program?

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APPENDIX A

FREQUENTLY ASKED QUESTIONS ABOUT ANIMAL CARE AND USE PROGRAMS

A.1. How shall institutional administrators gather data to evaluate the quality of the animal care and use program?

Starting with the premise that institutional administrators are knowledgeable about what constitutes a quality animal care and use program, it is then only necessary that they be provided with accurate data about their institution's programs. Such data may be obtained from a number of sources, such as:

-- The required Institutional Animal Care and Use Committee (IACUC) reports

-- Reports prepared by the United States Department of Agriculture (USDA) inspectors

-- Reports prepared by site visitors from extramural granting agencies (e.g., the National Institutes of Health (NIH))

-- Periodic briefings by the Animal Care Supervisor, Attending Veterinarian, and/or the Chairperson of the IACUC

-- Self-evaluation reports prepared at the request of the institutional administrator (see Appendix E, page 63 for a possible format)

-- Review of complaints or compliments relative to the animal care and use program (for this source of data to be useful, institutional procedures must be in place to document the complaints or compliments)

-- Reports prepared by external consultants (usually only required when there is a perception of chronic problems with the animal care and use program) or peer review organizations

Outside peer review of the animal care and use program by qualified personnel can be extraordinarily helpful in spotting problem areas which have been overlooked by in-house personnel. These outside reviews can be accomplished through contracts with private consultants or by participation in a voluntary accreditation program. At the time this publication was written, the only voluntary accrediting program in the United States is provided by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) (for details of the AAALAC program, see Appendix C, Section C.3., on page 52).

A.2 What are the pitfalls?

Laboratory animal science and medicine, as well as the laws and contemporary guidelines pertaining to laboratory animal care and use, are rapidly changing, leading to frequent, and often significant, changes. In addition, the public is expressing even stronger demands for accountability in programs publicly funded. These circumstances result in increased pressure on institutional administrators to re-evaluate and update their animal care and use programs at regular intervals. Major pitfalls to which institutional administrators should be alert are:

-- Absence of written clear lines of authority and responsibility
It is imperative that all those involved with the institution's animal care and use program understand and accept their individual and collective responsibilities. It must be known by all those involved exactly where "the buck stops."

-- Complacency
The concept of "That's the way we have always done it, so why change now?" is a trap which will most likely lead to obsolescence and other problems. Strong leadership by senior officials is a strong antidote to complacency.

-- Forgetting the in-house "community"
Ignoring the concerns of the institutional staff, or simply not having procedures which will permit staff to express concerns, can lead to frustrated employees who then seek help from extramural groups such as the news media.

-- Lack of information
Institutional administrators must ensure that they will be fully informed about the quality and effectiveness of their animal care and use programs.

-- One-sided resolution of disputes between animal care staff and animal users
All disputes between the animal care staff and animal users must be fairly resolved on the merits of the case and not on the relative prestige or income producing abilities of the persons in conflict.

-- Failure to have in place clearly well-written, well-publicized policies pertaining to the use of animals especially with regard to teaching programs
There is an increasingly vocal but small minority of students refusing to take part in academic exercises involving either live or dead animals (e.g., dissection of preserved animals in a biology class). Academic institutions should consider having written policies on student participation in exercises involving animals, including any available alternatives and the potential penalties, if any, for failure to participate. These policies should be clearly set forth in institutional catalogs and course materials.

A.3 How can professional staff be encouraged to support the animal care and use program?

The best way for institutional administrators to encourage professional staff support of the animal care and use program is by their own, highly visible support. Combining this with positive incentives, such as the use of discretionary funds to "underwrite"

improved animal care systems and the incorporation of investigator input into program management policies and procedures, will usually be sufficient to obtain support from animal users.

A.4 Why does the animal care and use program seem to cost so much?

Coincident with other costs of biomedical research and education, the costs of animal care and use programs are escalating. Just as the costs for biomedical equipment and library subscriptions have risen sharply over the last several decades, so too have the costs for animals, animal transportation, and animal housing. The animal care facility is an extension of the research laboratory, its sophistication should be consistent with the changing requirements of modern science.

Modern research requires the use of very sophisticated animal models which require more specialized care. The need for more finely tuned control of ambient environmental conditions required by these animals, the ability to detect even more subtle physiological changes (e.g., those caused by slight variations in husbandry conditions), and increasingly high standards contained in regulations and policies, have increased the cost of animal use significantly.

As husbandry and veterinary care requirements have become more complex, specially trained animal care professionals and technicians have become a necessity, and these persons command higher salaries than those traditionally paid for animal care providers. For example, the relatively inexpensive galvanized cage systems of yesteryear have been replaced with the considerably more expensive, and durable, plastic, stainless steel, or aluminum systems of today.

A.5 What is the United States Department of Agriculture (USDA) and its role in enforcing the Federal Animal Welfare Act?

The Federal Animal Welfare Act (7 U.S.C. 2131) is enforced by inspectors from the Animal and Plant Health Inspection Service (APHIS) of the U. S. Department of Agriculture (USDA) through

unannounced on-site inspections. The Animal Welfare Act requires all registered facilities to be inspected at least annually and more often if necessary to resolve deficiencies. The inspectors have broad powers to inspect facilities used to house "Act species" (i.e., dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, marine mammals, and other warm-blooded animals specified by the Secretary of Agriculture) and review reports of the IACUC. Penalties for violations of the Act include fines and imprisonment and, in conjunction with other Federal funding agencies, loss of Federal funds.

The USDA inspector will leave an inspection report entitled, "USDA Form 18-8," after each visit. It is then the institution's right to note any rebuttal comments to any alleged deficiencies or violations directly on the form, or on a separate page attached to the report, at the time of the inspection. Since all inspection reports are available to the general public through the Freedom of Information Act (see "What is the Impact of the Freedom of Information Act?," Appendix A, Section A.6, page 35), it may be very beneficial to ensure that any deficiency or violation which is thought to be unjustified by institutional personnel be rebutted at the time of the inspection, preferably directly on the form. A follow-up rebuttal may not be released with an inspection report if it is not made a part of that inspection record.

All registered institutions must submit an annual report detailing their use of species covered by the Act. Failure to submit the report may be grounds for legal penalties.

A.6 What is the impact of the Freedom of Information Act (FOIA)?

The Freedom of Information Act (FOIA, 5 U.S.C. 552) compels Federal agencies to release official documents except in a few specific cases, mostly pertaining to national security, Federal investigations, and personnel information. The provisions of this Act apply to both the USDA Federal investigations and all components of the Public Health Service (PHS); thus, nearly all material pertaining to animal care and use programs which are held by these agencies are obtainable through FOIA requests,

including the USDA inspection reports and the PHS Assurance Statements. The only exceptions to this are in cases of ongoing investigations into alleged violations of the Animal Welfare Act (AWA) or PHS Policy, in which case all relevant documents are protected from release; but only until the investigation is completed, at which time the entire case file may be subject to release. Because of the FOIA, and in order to protect the institution, its programs, and its employees, it is prudent for institutions to ensure that information, beyond that required, is not provided to any Federal agency. In addition, it would be prudent to ensure that where information is available in Federal files, e.g., the USDA inspection reports, that any rebuttal material or information is made an integral part of the files.

A.7 What is the concept of "animal rights?"

Until the mid-1970s, the philosophical foundation of the antivivisection movement was generally one of animal "welfare." However, since the mid-1970s the movement's philosophical foundation appears to have moved appreciably toward assertion of animal "rights." The concept of animal "rights" is variously defined but, in general, it can be understood to mean that sentient animals, especially warm-blooded vertebrates, have a "right" not to be used for research, i.e., such animals are not to be used as means to human ends. The more radical animal "rights" believers advocate the total abolition of all use of nonhuman animals for human benefit, e.g., for food, clothing, sport, or companionship.

The importance of this change in the philosophical foundation of the antivivisection movement lies in the fact that traditional animal "welfare" advocates can accept a high quality animal care and use program while animal "rights" advocates cannot. In other words, animal "welfare" advocates and scientists can usually find agreeable solutions to questions about how animals are to be cared for and used in biomedical research, testing, and education programs since both may be truly interested in the humane treatment of the animals. However, it would appear highly unlikely that extreme animal "rights" advocates and scientists can

reach agreement in the foreseeable future, as the only acceptable position for the "rightist" is total abolition of such use of animals. Because of this significant change in the philosophical foundation of the antivivisection movement, it is unlikely that the public concern over the use of animals in biomedical research, testing, and education programs will diminish markedly in the near future.

It should be noted, however, that by mandating research programs involving animals, the Congress of the United States, speaking on behalf of the people, has taken a firm stand against the animal "rights" advocates who would prohibit all use of animals for research purposes.

Furthermore, by refusing to incorporate animal "rights" language in any Federal legislation the Congress has withheld public approval for the animal "rights" philosophy.

APPENDIX B

LAWS AND GUIDELINES

APPENDIX B - LAWS AND GUIDELINES

B.1 Declaration of Helsinki
B.2 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (Principles)
B.3 Federal Animal Welfare Act
B.4 Public Health Service Policy
B.5 The NIH Guide for the Care and Use of Laboratory Animals
B.6 Good Laboratory Practice Regulations
B.7 Other Federal Laws
B.8 Guide for the Care and Use of Agriculture Animals in Agricultural Research and Teaching

APPENDIX B

LAWS AND GUIDELINES

B.1 Declaration of Helsinki

I. Basic Principles; Paragraph 1 - "Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal (emphasis added) experimentation and on a thorough knowledge of the scientific literature." [Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and as revised by the 29th World Medical Assembly, Tokyo, Japan, 1975. Revised in Budapest, 1983.]

B.2 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (Principles)

The Interagency Research Animal Committee, with representatives from all Federal agencies which fund biomedical research, developed a set of nine principles which are to be adhered to by institutions and persons using animals in Federally funded programs. The Principles are listed in the back of the Public Health Service (PHS) Policy document (see Appendix B, Section B.4., "Public Health Service Policy," on page 42). The preamble to the Principles states:

> "The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, [these] principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to."

B.3 Federal Animal Welfare (AWA) Act

The Federal Animal Welfare Act (7 U.S.C. 2131 et seq.) was passed in 1966 and has been amended three times since then; the latest in 1985 (P.L. 99-198 entitled, "The Improved Standards for Laboratory Animals Act"). The law applies to all institutions which use warm-blooded species included in the Act (dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, marine mammals, livestock species used for biomedical research, and warm-blooded wild mammals) or specified by the Secretary of Agriculture (thus far, the Secretary has not specified that any species be added to the list). In practice, the vast majority of institutions which use warm-blooded vertebrate animals in biomedical research, testing, and education programs are covered by the Federal law and must register with the USDA. All registered institutions are subject to annual inspections by USDA officers (more frequently if significant deficiencies are noted) and must have an Institutional Animal Care and Use Committee (see Table 1 for Committee composition and responsibilities, pages 75-77). Copies of the current implementation regulations and any pending revisions can be obtained from:

Animal and Plant Health Inspection Service
United States Department of Agriculture
Room 756, Federal Building
6505 Belcrest Road
Hyattsville, MD 20782
(301) 436-7833

B.4 Public Health Service (PHS) Policy

The PHS Policy on the Care and Use of Laboratory Animals has been in existence for many years and was significantly revised in 1985 and, most recently, in 1986. The September 1986 revision includes provisions mandated by Federal law (P.L. 99-158, Health Research Extension Act of 1985). All institutions which receive PHS funds for "research, research training, and biological testing activities" involving the use of vertebrate animals, including funds

from the National Institutes of Health, are required to adhere to the provisions of the PHS Policy, regardless of the species of vertebrate animal used.

A major provision of the PHS Policy is the requirement for institutions to file an "Animal Welfare Assurance" with the Office for Protection from Research Risks (OPRR). Before any PHS funds may be awarded to an institution it must have an approved Assurance on file with OPRR. The Assurance must include a detailed description of the institution's animal care and use program and implementing procedures for the program, as well as documentation of institutional commitment to adherence to the PHS Policy. In addition, an annual report to OPRR is required indicating any changes in the animal care and use program as reported in the Assurance, dates of semiannual Institutional Animal Care and Use Committee (IACUC) reports required by the Policy, gain or loss of American Association for Accreditation of Laboratory Animal Care (AAALAC) Accreditation, and any minority views on the findings in required reports. Animal Welfare Assurance documents constitute institutional policy and must be promulgated to all persons who participate in the animal welfare program of the institution.

The PHS Policy also requires institutions using animals and submitting research grant proposals to have an IACUC (see Table 1, on page 75 for composition and responsibilities of the committee) to ensure that the following five points have been addressed in the applications, with sufficient detail to permit evaluation, and to verify IACUC approval:

(1) The species and number of animals required, including justification for the numbers proposed.

(2) The rationale for the use of living animals in general, and of the specific animal model system proposed in particular.

(3) A description of how the animals will be housed and used and what procedures they will be involved in.

(4) A description of any procedures which will be utilized to minimize pain and distress.

(5) A description of the methods of euthanasia which will be used.

Copies of the current Policy may be obtained from:

Office for Protection from Research Risks (OPRR)
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
(301) 496-7163

B.5 The NIH Guide for the Care and Use of Laboratory Animals (Guide)

The Guide for the Care and Use of Laboratory Animals (the Guide, NIH Publication 85-23) is the most influential set of guidelines pertaining to laboratory animal care and use in existence. The Guide is intended to be a source of "information on common laboratory animals housed under a variety of circumstances" which will "assist institutions in caring for and using laboratory animals in ways judged to be professionally and humanely appropriate." All persons involved with administering an animal care and use program should be fully familiar with the provisions of the Guide. It was first published in 1963 and has been revised five times, most recently in 1985. The contents of the Guide are developed by a panel of veterinary and other scientific experts assembled by the Institute of Laboratory Animal Resources (ILAR), Commission on Life Sciences, National Research Council, and the National Academy of Sciences and represent contemporary consensus on appropriate standards for Animal Care and Use Programs.

The contents of the Guide include sections covering Institutional Policies, Laboratory Animal Husbandry, Veterinary Care, Physical Plant, and Special Considerations. In addition, there are four Appendices which include a Selected Bibliography, a listing of

Professional and Certifying Laboratory Animal Science Organizations, a selected list of Federal Laws Relevant To Animal Care and Use, the PHS Policy, and the U.S. Government Principles.

The Guide is published by NIH and copies are available from OPRR (for address, see page 44).

B.6 Good Laboratory Practice (GLP) Regulations

Both the Food and Drug Administration (21 C.F.R. 58) and the Environmental Protection Agency (40 C.F.R. 160 for Pesticide Program and 40 C.F.R. 792 for Toxic Substances Program) enforce Federal regulations requiring the use of "Good Laboratory Practices" (GLPs). The provisions of these regulations contain specific requirements for the care and housing of laboratory animals as well as for documentation of such care and use. These regulations apply only to projects being accomplished which will result in data supporting new drug or medical devices and new pesticide or toxic substances applications, respectively. Institutions conducting research projects which fall into these categories should obtain (a) copy(ies) of the appropriate GLP(s) and ensure that the provisions thereof are followed. Copies of the current GLPs may be obtained from:

Food and Drug Administration
Bioresearch Program Office
Parklawn Building, Room 12A-55
HFC-230
5600 Fishers Lane
Rockville, MD 20857
(301) 443-2390

Environmental Protection Agency
Office of Pesticides and Toxic Substances
Laboratory Data Integrity Programs
401 M Street, SW
Washington, DC 20460
(202) 382-7830

B.7 Other Federal Laws

a. Marine Mammal Conservation and Protection Act

The Marine Mammal Conservation and Protection Act (16 U.S.C. 1361) applies to any program maintaining marine mammals in captivity or interacting with marine mammals in the wild. The Act includes provisions for housing, handling, and care of marine mammals which are in addition to the marine mammal standards included in the Animal Welfare Act (AWA). Any institution with programs involving marine mammals should be familiar with the provisions of this Act. Copies of the current law and regulations may be obtained from:

Department of the Interior
Fish and Wildlife Service
18th & C Streets, NW
Washington, DC 20240
(202) 343-5634

b. Lacey and Endangered Species Acts (and Convention on International Trade in Endangered Species (CITES)

The Lacey Act (16 U.S.C. 701) applies to programs involving the interstate transport of wild animals captured in any of the 50 states. The Endangered Species Act (16 U.S.C. 1531) applies to specified species of animals, sometimes from specified geographic areas, which have been determined to be "endangered" or "threatened." The provisions of the Endangered Species Act may apply to captive bred, as well as wild-caught, individuals of the listed species. Institutions using wild caught or nondomestic animals, including most species of nonhuman primates, should be familiar with the provisions of these Acts and the latest version of the CITES. Institutions procuring or shipping animals in international trade may also be impacted by the provisions of the Convention on International Trade in Endangered Species (CITES, 27 U.S.T. 1087, TIAS 8249) if the species involved are covered by the provisions of the Convention. Copies of the current laws,

regulations, and Convention may be obtained from the Fish and Wildlife Service of the Department of the Interior at the address listed in Appendix B, under Section B.7.a., on page 46.

c. Guidelines and Regulations for Recombinant DNA, Biohazardous Agents, Hazardous Chemicals, Radiation Producing Equipment, Radioactive Materials, and Controlled Substances

Various Federal and state agencies, issue a number of guidelines, and in some cases regulations (e.g., Nuclear Regulatory Commission regulations pertaining to radioisotope possession and use), which impact upon an institution's animal care and use program. Whenever such materials or equipment are involved in an institution's research, testing, or education programs involving animals, the appropriate institutional safety or assurance officials and committees should be aware of their use and of all appropriate Federal and state regulations and guidelines. It is also especially important that the animal care supervisor be knowledgeable about any special requirements for animal housing or handling and ensure that appropriate safety precautions are implemented by all persons working with the animals involved. Some selected sources for information about Federal regulations and guidelines listed below are:

Carcinogens, Chemicals, and R-DNA:	National Institutes of Health Division of Safety Building 31, Room 1C02 Bethesda, MD 20892 (301) 496-1357
Infectious Agents:	Centers for Disease Control Office of Biosafety Atlanta, GA 30333 (404) 329-3883

Isotopes:	U.S. Nuclear Regulatory Commission Medical, Academic, and Commercial Use Safety Branch WF1, Mail Stop 6H06 Washington, DC 20555 (202) 492-0640
Radiation, and Medical Devices:	Food and Drug Administration Center for Devices and Radiological Health HFZ-311 1390 Piccard Drive Rockville, MD 20850 (301) 427-1165
Safety and Health:	Department of Labor Occupational Safety and Health Administration 200 Constitution Ave, NW Washington, DC 20210 (202) 523-7075/8063

B.8 Guide for the Care and Use of Agriculture Animals in Agricultural Research and Teaching

While not covered by any law, regulation, or Federal policy, the care and use of agricultural animals for agricultural research not funded by Federal agencies is of concern to a number of organizations and institutions. As a result of these concerns, the agricultural community appointed a Consortium for Developing a Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide). The First Edition of the Agri-Guide was published in March 1988 and is available from the American Dairy Science Association, 309 West Clark Street, Champaign, IL 61820. Institutions using livestock species for agricultural research will find this new set of guidelines especially useful.

APPENDIX C

SELECTED RESOURCE SOURCES

APPENDIX C - SELECTED RESOURCE SOURCES

C.1 National Library of Medicine (NLM)
C.2 National Agricultural Library (NAL)
C.3 American Association for the Accreditation of Laboratory Animal Care (AAALAC)
C.4 Institute of Laboratory Animal Resources (ILAR)
C.5 American College of Laboratory Animal Medicine (ACLAM)
C.6 American Association for Laboratory Animal Science (AALAS)
C.7 American Veterinary Medical Association (AVMA)
C.8 National Association for Biomedical Research (NABR) and Foundation for Biomedical Research (FBR)

APPENDIX C

SELECTED RESOURCE SOURCES

C.1 National Library of Medicine (NLM)

The National Library of Medicine (NLM) is currently providing computer searches under the key phrase "Animal Welfare" through its MEDLINES services. In addition, NLM has a listing of training materials which may be useful for institutions which are developing in-house training programs. Additional information on NLM services may be obtained from:

Dr. Fritz Gluckstein
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
(301) 496-6097

C.2 National Agricultural Library (NAL)

As required by the 1985 Amendments of the Federal Animal Welfare Act (AWA), the National Agricultural Library (NAL) has established a reference service for materials which document "alternative" procedures to animal use in biomedical research, testing, and teaching, as well as for the development of in-house training programs. In addition, an on-line electronic bulletin board and mail service has been initiated at the NAL. Information on NAL programs and materials may be obtained from:

Ms. Jean Larson
National Agricultural Library
Beltsville, MD 20705
(301) 344-1215

C.3 American Association for the Accreditation of Laboratory Animal Care (AAALAC)

The American Association for Accreditation of Laboratory Animal Care (AAALAC) was established in 1965 as a cooperative effort between several professional societies and has achieved a reputation for the quality of its accreditation program. The program involves an initial site visit followed by revisits at least every three years. AAALAC chooses qualified site visitors to evaluate animal care and use programs and AAALAC Accreditation is considered by most people, including the PHS, an indication that an institution has and is committed to maintaining an overall high quality Animal Care and Use Program. Information about the AAALAC program may be obtained from:

Dr. Albert E. New
Executive Director
American Association for Accreditation of
Laboratory Animal Care
9650 Rockville Pike
Bethesda, MD 20814
(301) 571-1850

C.4 Institute of Laboratory Animal Resources (ILAR)

The Institute of Laboratory Animal Resources (ILAR), National Research Council, National Academy of Sciences, currently provides information on sources of species and strains of animals; publishes various standards for nomenclature, housing, and handling of laboratory animals; accomplishes national surveys on the use of animals in biomedical research, testing, and education; and sponsors symposia and reports on various specific topics of interest (e.g., the use of "alternatives" to animals). Information on current activities may be obtained from:

Dr. Thomas L. Wolfle
Director
Institute of Laboratory Animal Resources
National Research Council
National Academy of Sciences
2101 Constitution Ave, NW
Washington, DC 20418
(202) 334-2590

C.5 American College of Laboratory Animal Medicine (ACLAM)

The American College of Laboratory Animal Medicine (ACLAM) is a veterinary specialty board. Members, or Diplomates, are veterinarians who have met specific training/experience criteria and have successfully completed an examination in Laboratory Animal Medicine and Science. Additional information about the ACLAM may be obtained from:

Dr. C. Max Lang
Secretary Treasurer
American College of Laboratory Animal Medicine
Department of Comparative Medicine
The Milton S. Hershey Medical Center
The Pennsylvania State University
P.O. Box 850
Hershey, PA 17033
(717) 531-8462

C.6 American Association for Laboratory Animal Science (AALAS)

The American Association for Laboratory Animal Science (AALAS) is a professional society with membership open to anyone interested in the field of Laboratory Animal Science. The Association administers a national certification program for laboratory animal care technicians and managers. Certification is obtained by successful completion of examinations given on a nationwide basis. AALAS also produces and sells or loans training materials pertaining to laboratory animal care, handling, and housing. Information about the AALAS may be obtained from:

Mr. Donald Keene
Executive Director
American Association for Laboratory Animal Science
70 Timber Creek Drive, Suite 5
Cordova, TN 38018
(901) 754-8620

C.7 American Veterinary Medical Association (AVMA)

The American Veterinary Medical Association (AVMA) is a professional society with membership open to veterinarians and selected other persons who have made significant contributions to Veterinary Medicine. The AVMA accredits college-level programs in veterinary technology, many of which provide training relevant to laboratory animal science. In addition, the Association produces and distributes audiovisual materials which are useful for laboratory animal training programs. Information about AVMA programs may be obtained from:

American Veterinary Medical Association
930 North Meacham Road
Schaumberg, IL 60196
(800) 248-2862

C.8 National Association for Biomedical Research (NABR) and Foundation for Biomedical Research (FBR)

The National Association for Biomedical Research (NABR) is an association of institutional members interested in supporting the appropriate use of animals in biomedical research. NABR engages in numerous lobbying efforts and provides its member institutions with legislative updates and public education materials. Individual memberships are not accepted.

The Foundation for Biomedical Research (FBR) is a nonprofit, educational organization established for the purpose of developing and distributing educational materials for use in Laboratory Animal Science and Public Awareness Programs. In addition, FBR

provides its contributors with up-to-date information on current issues involving the use and care of laboratory animals. Individual contributions are accepted. Both organizations may be reached at the following address:

National Association for Biomedical Research
[Foundation for Biomedical Research]
818 Connecticut Ave, NW
Washington, DC 20006
NABR - (202) 857-0540
FBR - (202) 457-0654

APPENDIX D

OCCUPATIONAL HEALTH PROGRAM

APPENDIX D - OCCUPATIONAL HEALTH PROGRAM

D.1 History and Physical Examinations
D.2 Education Program
D.3 Monitoring and Immunization Schedules
D.4 Occupational Health Program
D.5 Occupational Health Professional

APPENDIX D

OCCUPATIONAL HEALTH PROGRAM

The Guide for the Care and Use of Laboratory Animals (the Guide, NIH Publication 85-23) states that "an occupational health program is mandatory for personnel who work in laboratory animal facilities or have substantial animal contact." The components of an acceptable Occupational Health Program include:

D.1 History and Physical Examinations

a. A medical history and preemployment physical examination should be completed prior to anyone being allowed to work with animals. Persons with evidence of diseases transmissible to animals (e.g., tuberculosis), allergies to animals, or who may be immune deficient should be discouraged, or prohibited, from working with animals.

b. Periodic physical examinations should be completed where circumstances warrant, e.g., routine exposure to potentially hazardous situations such as working with nonhuman primates, in high noise areas, or with ionizing radiation. These periodic examinations should be customized as appropriate for the circumstances, e.g., audiometry for persons working in high noise areas.

c. Special physical examinations may be necessary due to nonroutine exposure to a hazardous situation, e.g., a bite from a rhesus monkey possibly infected with simian herpes virus. These examinations should be limited to procedures necessary for monitoring the patient for the health hazard involved.

D.2 Education Program

An ongoing educational program should be in place which ensures that all persons working in an Animal Care and Use Program are fully aware of any potential hazards involved in their work, e.g., physical dangers involved with the species in use (such as bites, scratches, and allergies), zoonotic organisms, chemical

and radiation hazards, and general safety hazards (such as slippery floors, use of live steam in sanitization and sterilization equipment, and lifting of heavy objects). In addition, the education program should ensure that all persons working with animals know how to recognize, prevent, and treat occupational hazards.

D.3 Monitoring and Immunization Schedules

Appropriate monitoring and immunization schedules should be adopted.

a. Monitoring should include biannual PPD tuberculin skin testing (only for persons with nonhuman primate contact and who have been PPD negative), rabies titers (for persons immunized for rabies and who are exposed to wild mammals or random source dogs and cats), Q-fever titers (for persons exposed to sheep, goats, cattle, and pigs), and, where possible, titers for any infectious agents involved in the research.

b. Serum samples should be collected for banking prior to employment, at periodic intervals during employment, and at termination of employment. Samples should be stored at liquid nitrogen temperatures for reference use in the case of suspected zoonotic illness and should be kept permanently.

c. An immunization program should be an integral part of the Occupational Health Program and should include a mandatory requirement for vaccination for tetanus (preemployment and at 10 year intervals), along with voluntary vaccinations for rabies (for persons exposed to wild mammals and random source dogs and cats) and research specific organisms as appropriate (e.g., hepatitis B, vaccinia virus constructs, and tularemia).

D.4 Occupational Health Program

The Occupational Health Program should include procedures for monitoring and detecting occupationally caused illness or injury. Records should be kept, and maintained permanently, of work

assignments, exposure to hazardous agents, injuries (especially animal bites and scratches), and unusual illnesses.

D.5 Occupational Health Professional

A qualified Occupational Health Professional should review the Occupational Health Programs and records on a regular basis.

APPENDIX E

SELF-EVALUATION OUTLINE

APPENDIX E - SELF-EVALUATION OUTLINE

E.1 Institutional Policies
E.2 Laboratory Animal Husbandry
E.3 Veterinary Care
E.4 Physical Plant
E.5 Special Considerations

APPENDIX E

SELF-EVALUATION OUTLINE

NOTE TO READER: The following outline is based on the NIH Guide for the Care and Use of Laboratory Animals (Guide) and is intended only to illustrate the types of questions which should be included in any self-evaluation of an animal care and use program. It is not intended to be all-inclusive and persons responsible for such an evaluation should be fully familiar with the provisions of the Guide and modify this outline accordingly as appropriate for their institution. In all cases, descriptions called for in the outline should be concluded with statements as to whether or not the component described meets the provisions of the Federal Animal Welfare Act and the Guide. Institutional administrators reviewing the self-evaluation reports also should be fully familiar with the provisions of the Guide so that they are able to judge the adequacy of their animal care and use programs.

E.1 Institutional Policies

1. Is there a written statement of institutional commitment to appropriate and humane animal care and use? If yes, indicate where it has been published and attach a copy.

2. What procedures are there for reviewing and monitoring the care and proposed, and ongoing, use of animals in institutional programs? Are there mechanisms for suspending questionable procedures or projects until reviewed by the Institutional Animal Care and Use Committee (IACUC) or a senior administrative official? If yes, describe.

3. Describe the veterinary care program. Include a description of the provisions for emergency, after-hours care, and how an investigator would obtain such care. What are the responsibilities and authority of the attending veterinarian?

4. Describe the qualifications of the principal animal care managers and indicate how the qualifications of the animal users are determined.

5. Describe the Occupational Health Program for persons working with animals, including any requirements pertaining to the use of personal protective equipment and personal hygiene procedures. Describe the criteria by which it is determined who will be included or excluded from the Occupational Health Program.

6. Describe any institutional policies pertaining to the use of hazardous agents in laboratory animals.

7. Describe any institutional policies pertaining to long-term restraint or multiple surgical procedures.

E.2 Laboratory Animal Husbandry

1. Provide a general description of each animal housing facility, including its present state of repair. Indicate what minor and major repairs, if any, are required. Include a discussion of any new facilities, or major remodeling efforts, which are necessary to bring the animal care and use program into compliance with current laws, regulations, or guidelines.

2. Describe the routine housing arrangements for each species being used in institutional programs. Include types of cages and bedding, caging densities, provisions for feeding and watering (including on weekends and holidays), environmental conditions (e.g., temperature, humidity, and light cycles), sanitation schedules, and methods of identification and record keeping.

3. Describe any special housing arrangements required by specific research programs.

4. Summarize the provisions for emergency, weekend, and holiday care.

E.3 Veterinary Care

1. If not done in Section E.I, describe the overall veterinary care program.

2. Describe the Preventive Medicine Program. Include discussions of animal procurement, quarantine, and species separation procedures and policies intended to minimize risks of introducing, or spreading, diseases into, or among, institutional colonies.

3. Describe the procedures and policies for disease surveillance, diagnosis, treatment, and control.

4. Describe the policies pertaining to the use of anesthetics, analgesics, and tranquilizers for elimination or minimization of animal pain and distress. Include specific discussions on any procedures approved by the IACUC which involve unrelieved animal pain or distress.

5. Describe the policies and procedures pertaining to surgery and post-surgical care. Include specific discussions about the level of asepsis required for which kinds of surgical procedures, in which species of animals, and about the adequacy of facilities used for survival surgery.

6. Describe the methods of euthanasia approved for use with each of the species involved in institutional programs.

E.4 Physical Plant

1. Indicate what the physical relationship is between the animal facilities, support facilities, research laboratories, and teaching laboratories.

2. Describe what functional areas are included in the animal facilities or are available for use by animal care or use personnel.

3. If not included with the general description of facilities provided in Part E.2.1., on page 66, provide descriptions of the

following aspects of the animal facilities: corridor size and construction, animal room door design and condition, animal room surfaces (floors, walls, ceilings), lighting (windows, light fixtures, light intensity, timers), temperature and humidity control, ventilation, power (including provisions for power outages), noise control, storage space, equipment and supply sanitation capabilities, and provisions for monitoring environmental parameters.

4. Describe any facilities used for aseptic surgery.

5. Describe any facilities used for animal research involving hazardous agents (e.g., infectious organisms, carcinogenic or toxic chemicals, and radioisotopes).

6. Although not specifically addressed in the Guide or in the PHS Policy, security of the animal facilities and research laboratories is an area of distinct importance. Each research facility needs a precise and deliberate approach to dealing with the risk of physical damage to facilities, records, and equipment, or pilferage of animals or research records. Describe any existing security systems or procedures and note any known deficiencies. If resources are available to make a formal risk assessment report, attach a copy.

E.5 Special Considerations

1. Describe the procedures used to monitor and assure animal genetic and nomenclature accuracy.

2. Describe the policies, procedures, and activities involving animals not currently covered by the Federal Animal Welfare Act, Public Health Service Policy, or the Guide.

3. Describe what Federal, state, and local laws, regulations, and guidelines affect the institution's Animal Care and Use Programs. Are any special permits or licenses required and have they been obtained? Do all of the institution's policies and procedures comply with all applicable laws, regulations, and guidelines? If not, describe the discrepancies.

APPENDIX F

ACRONYMS OF ORGANIZATIONS AND
REGULATORY REFERENCES INCLUDED IN THIS MANUAL

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ACRONYM	ORGANIZATION OR REGULATORY REFERENCE
AAALAC	American Association for the Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
ACLAM	American College of Laboratory Animal Medicine
AGRI-GUIDE	Guide for the Care and Use of Agricultural Animals in Argricultural Research and Teaching
APHIS	Animal and Plant Health Inspection Service
AVMA	American Veterinary Medical Association
AWA	Animal Welfare Act
CITES	Convention on International Trade in Endangered Species
FBR	Foundation for Biomedical Research
FOIA	Freedom of Information Act
GLP	Good Laboratory Practice
GUIDE	Guide for the Care and Use of Laboratory Animals
IACUC	Institutional Animal Care and Use Committee
ILAR	Institute of Laboratory Animal Resources

LACEY	Lacey and Endangered Species Act
MANUAL	Institutional Administrator's Manual for Laboratory Animal Care and Use
NABR	National Association for Biomedical Research
NAL	National Agricultural Library
NAS	National Academy of Science
NIH	National Institutes of Health
NLM	National Library of Medicine
NRC	National Research Council
OPRR	Office for Protection from Research Risks
PHS	Public Health Service
PHS POLICY	Public Health Service Policy on Humane Care and Use of Laboratory Animals
PRINCIPLES	U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
USDA	United Stated Department of Agriculture

TABLE 1

INSTITUTIONAL ANIMAL CARE AND
USE COMMITTEES

TABLE 1 - INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

1. Appointing Official
2. Membership
3. Responsibility

TABLE 1

Table 1 entitled "Institutional Animal Care and Use Committees,"is designed to compare provisions of the Federal Animal Welfare Act and the Public Health Service Policy regarding the areas of Appointing Authority, Membership, and Responsibilities.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEES

FEDERAL ANIMAL WELFARE ACT	PUBLIC HEALTH SERVICE POLICY
1. APPOINTING AUTHORITY	
"Chief Executive Officer" of the research facility.	"Chief Executive Officer" of the research facility.
2. MEMBERSHIP	
Not less than three members with "sufficient ability to assess animal care, treatment, and procedures." At least one member shall be a veterinarian and at least one shall not be affiliated with the institution other than for service on the Committee (and shall not be a member of the immediate family of a person who is affiliated with the institution) and who is to "provide representation for general community interests in the proper care and treatment of animals." If the Committee consists of more than three members, no more than three shall be from the same administrative unit of the institution.	Not less than five members "qualified through experience and expertise" to oversee the institution's animal program, facilities, and procedures. The committee membership shall include at least one veterinarian ("with training or experience in Laboratory Animal Science and Medicine"), one practicing scientist ("experienced in research involving animals") one nonscientist, and one person not affiliated with the institution except for service on the Committee (and who is not a member of the immediate family of a person affiliated with the institution). An individual who meets the requirements of more than one of the categories may fulfill more than one requirement.

3. RESPONSIBILITIES

- At least semiannually inspect all animal study areas and animal facilities.

- During the inspections, review: (a) "practices involving pain to animals" and (b) the condition of animals.

- File inspection reports with the institution (must be retained for at least three years and be available for inspection of USDA inspectors); reports must (a) be signed by a majority of the Committee members involved in the inspection, (b) include reports of violations or deficiencies pertaining to the standards and deviations from approved procedures, (c) include any minority views, and (d) include any other information pertinent to the activities of the Committee.

- Notify the "adminstrative representative of the research facility of any deficiencies or deviations from the provisions of [the] Act" and, if after an opportunity for correction, the deficiencies or deviations remain uncorrected, notify USDA/APHIS (in writing) and the funding Federal agency of such deficiencies and deviations.

As pertain to PHS supported activities:

- At least semiannually inspect animal facilities using the Guide as a basis for evaluation.

- In addition to inspecting the facilities, the Committee is expected to review the "institution's program for humane care and use" during these twice yearly reviews.

- Submit reports of the semiannual evaluations with the "Institutional Official" (person signing NIH Assurance Letter), such reports to be "maintained by the institution and made available to OPRR upon request" (retention period not given); reports must (a) be udpated at least every six months, (b) include a description of the "nature and extent of the institution's adherence to the Guide and [the PHS] Policy and must identify specifically any departures from the provisions of the Guide and [PHS] Policy, and must state the reasons for each departure, (c) distinguish between "significant" and "minor" deficiencies (significant being any which threatens the health or safety of the animals), (d) include a plan for correcting

3. RESPONSIBILITIES (Cont'd)

- Federal facilities will establish committees as specified above and which will function as noted above except that they will report uncorrected deficiencies or deviations to the head of the Federal agency involved and not to USDA/APHIS.

each deficiency, and (e) identify any element of the institution holding AAALAC Accreditation.

- Notification of the "institutional official" as per previous paragraph.

- "Review concerns involving the care and use of animals at the institution."

- Make recommendations regarding all aspects of the institution's animal program, facilities, or personnel training.

- Review and approve, require modifications in (to secure approval), or withhold approval of activities, or proposed significant changes to previously approved, activities supported by PHS funds. All approved activities must be rereviewed at least every three years.

- Suspend a previously approved activity involving animals if it is determined that the activity is not being conducted in accordance with the Federal Animal Welfare Law, the Guide, or the PHS Policy.

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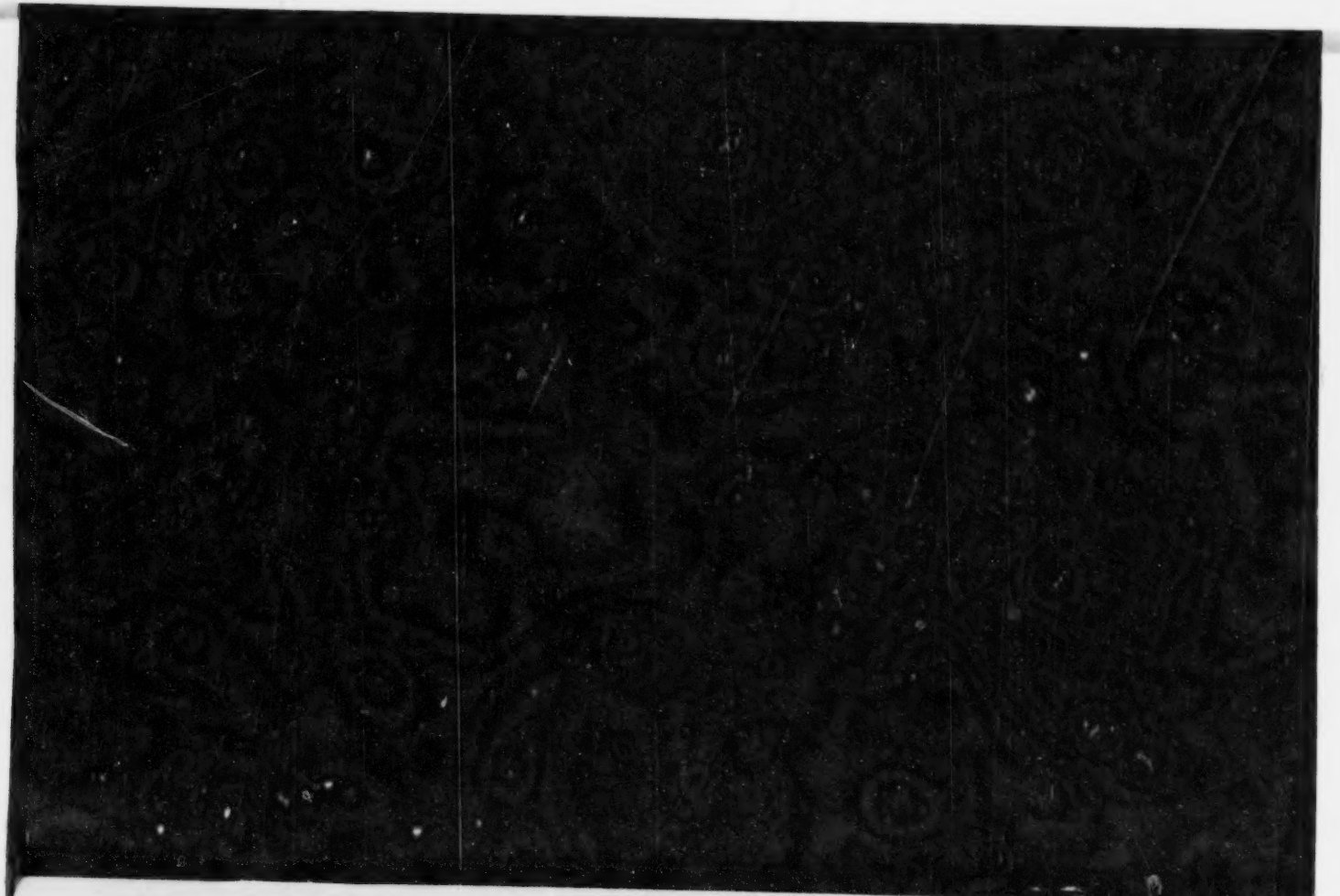

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